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# Moxifloxacin in Pediatric Patients With Complicated Intra-abdominal Infections: Results of the MOXIPEDIA Randomized Controlled Study

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## Abstract

**Background:**
This study was designed to evaluate primarily the safety and also the efficacy of moxifloxacin (MXF) in children with complicated intra-abdominal infections (cIAIs).

**Methods:**
In this multicenter, randomized, double-blind, controlled study, 451 pediatric patients aged 3 months to 17 years with cIAIs were treated with intravenous/oral MXF (N = 301) or comparator (COMP, intravenous ertapenem followed by oral amoxicillin/clavulanate; N = 150) for 5 to 14 days. Doses of MXF were selected based on the results of a Phase 1 study in pediatric patients (NCT01049022). The primary endpoint was safety, with particular focus on cardiac and musculoskeletal safety; clinical and bacteriologic efficacy at test of cure was also investigated.

**Results:**

The proportion of patients with adverse events (AEs) was comparable between the 2 treatment arms (MXF: 58.1% and COMP: 54.7%). The incidence of drug-related AEs was higher in the MXF arm than in the COMP arm (14.3% and 6.7%, respectively). No cases of QTc interval prolongation-related morbidity or mortality were observed. The proportion of patients with musculoskeletal AEs was comparable between treatment arms; no drug-related events were reported. Clinical cure rates were 84.6% and 95.5% in the MXF and COMP arms, respectively, in patients with confirmed pathogen(s) at baseline.

**Conclusions:**

MXF treatment was well tolerated in children with cIAIs. However, a lower clinical cure rate was observed with MXF treatment compared with COMP. This study does not support a recommendation of MXF for children with cIAIs when alternative more efficacious antibiotics with better safety profile are available.



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